

**§ 862.1260 Estradiol test system.**

(a) *Identification.* An estradiol test system is a device intended to measure estradiol, an estrogenic steroid, in plasma. Estradiol measurements are used in the diagnosis and treatment of various hormonal sexual disorders and in assessing placental function in complicated pregnancy.

(b) *Classification.* Class I.

**§ 862.1265 Estriol test system.**

(a) *Identification.* An estriol test system is a device intended to measure estriol, an estrogenic steroid, in plasma, serum, and urine of pregnant females. Estriol measurements are used in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

(b) *Classification.* Class I.

**§ 862.1270 Estrogens (total, in pregnancy) test system.**

(a) *Identification.* As estrogens (total, in pregnancy) test system is a device intended to measure total estrogens in plasma, serum, and urine during pregnancy. The device primarily measures estrone plus estradiol. Measurements of total estrogens are used to aid in the diagnosis and treatment of fetoplacental distress in certain cases of high-risk pregnancy.

(b) *Classification.* Class I.

**§ 862.1275 Estrogens (total, nonpregnancy) test system.**

(a) *Identification.* As estrogens (total, nonpregnancy) test system is a device intended to measure the level of estrogens (total estrone, estradiol, and estriol) in plasma, serum, and urine of males and nonpregnant females. Measurement of estrogens (total, nonpregnancy) is used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea (absence of menses) differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

(b) *Classification.* Class I.

**§ 862.1280 Estrone test system.**

(a) *Identification.* An estrone test system is a device intended to measure estrone, an estrogenic steroid, in plas-

ma. Estrone measurements are used in the diagnosis and treatment of numerous disorders, including infertility, amenorrhea, differentiation of primary and secondary ovarian malfunction, estrogen secreting testicular and ovarian tumors, and precocious puberty in females.

(b) *Classification.* Class I.

**§ 862.1285 Etiocholanolone test system.**

(a) *Identification.* An etiocholanolone test system is a device intended to measure etiocholanolone in serum and urine. Etiocholanolone is a metabolic product of the hormone testosterone and is excreted in the urine. Etiocholanolone measurements are used in the diagnosis and treatment of disorders of the testes and ovaries.

(b) *Classification.* Class I.

**§ 862.1290 Fatty acids test system.**

(a) *Identification.* A fatty acids test system is a device intended to measure fatty acids in plasma and serum. Measurements of fatty acids are used in the diagnosis and treatment of various disorders of lipid metabolism.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

**§ 862.1295 Folic acid test system.**

(a) *Identification.* A folic acid test system is a device intended to measure the vitamin folic acid in plasma and serum. Folic acid measurements are used in the diagnosis and treatment of megaloblastic anemia, which is characterized by the presence of megaloblasts (an abnormal red blood cell series) in the bone marrow.

(b) *Classification.* Class II.

[52 FR 16122, May 1, 1987; 53 FR 11645, Apr. 8, 1988]

**§ 862.1300 Follicle-stimulating hormone test system.**

(a) *Identification.* A follicle-stimulating hormone test system is a device intended to measure follicle-stimulating hormone (FSH) in plasma, serum, and urine. FSH measurements are used in

the diagnosis and treatment of pituitary gland and gonadal disorders.

(b) *Classification.* Class I.

**§ 862.1305 Formiminoglutamic acid (FIGLU) test system.**

(a) *Identification.* A formiminoglutamic acid (FIGLU) test system is a device intended to measure formiminoglutamic acid in urine. FIGLU measurements obtained by this device are used in the diagnosis of anemias, such as pernicious anemia and congenital hemolytic anemia.

(b) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

**§ 862.1310 Galactose test system.**

(a) *Identification.* A galactose test system is a device intended to measure galactose in blood and urine. Galactose measurements are used in the diagnosis and treatment of the hereditary disease galactosemia (a disorder of galactose metabolism) in infants.

(b) *Classification.* Class I.

**§ 862.1315 Galactose-1-phosphate uridyl transferase test system.**

(a) *Identification.* A galactose-1-phosphate uridyl transferase test system is a device intended to measure the activity of the enzyme galactose-1-phosphate uridyl transferase in erythrocytes (red blood cells). Measurements of galactose-1-phosphate uridyl transferase are used in the diagnosis and treatment of the hereditary disease galactosemia (disorder of galactose metabolism) in infants.

(b) *Classification.* Class II.

**§ 862.1320 Gastric acidity test system.**

(a) *Identification.* A gastric acidity test system is a device intended to measure the acidity of gastric fluid. Measurements of gastric acidity are used in the diagnosis and treatment of patients with peptic ulcer, Zollinger-Ellison syndrome (peptic ulcer due to gastrin-secreting tumor of the pancreas), and related gastric disorders.

(b) *Classification.* Class I. The device is exempt from the premarket notification

procedures in subpart E of part 807.

[52 FR 16122, May 1, 1987, as amended at 53 FR 21449, June 8, 1988]

**§ 862.1325 Gastrin test system.**

(a) *Identification.* A gastrin test system is a device intended to measure the hormone gastrin in plasma and serum. Measurements of gastrin are used in the diagnosis and treatment of patients with ulcers, pernicious anemia, and the Zollinger-Ellison syndrome (peptic ulcer due to a gastrin-secreting tumor of the pancreas).

(b) *Classification.* Class I.

**§ 862.1330 Globulin test system.**

(a) *Identification.* A globulin test system is a device intended to measure globulins (proteins) in plasma and serum. Measurements of globulin are used in the diagnosis and treatment of patients with numerous illnesses including severe liver and renal disease, multiple myeloma, and other disorders of blood globulins.

(b) *Classification.* Class I.

**§ 862.1335 Glucagon test system.**

(a) *Identification.* A glucagon test system is a device intended to measure the pancreatic hormone glucagon in plasma and serum. Glucagon measurements are used in the diagnosis and treatment of patients with various disorders of carbohydrate metabolism, including diabetes mellitus, hypoglycemia, and hyperglycemia.

(b) *Classification.* Class I.

**§ 862.1340 Urinary glucose (non-quantitative) test system.**

(a) *Identification.* A urinary glucose (nonquantitative) test system is a device intended to measure glucosuria (glucose in urine). Urinary glucose (nonquantitative) measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, hypoglycemia, and hyperglycemia.

(b) *Classification.* Class II.

**§ 862.1345 Glucose test system.**

(a) *Identification.* A glucose test system is a device intended to measure glucose quantitatively in blood and